

CLINICAL RESEARCH REQUEST FOR APPLICATIONS: MUSIC THERAPY OR ART THERAPY WITH MILITARY POPULATIONS DATE OF RELEASE: MARCH 15, 2023

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I. MUSIC THERAPY OR ART THERAPY RESEARCH SUBAWARD OVERVIEW

SUBAWARD TITLE: Music Therapy or Art Therapy Research with Military Populations

OVERVIEW: The Creative Forces®: National Endowment for the Arts (NEA) Military Healing Arts Network is embarking on the next phase of research funding to address priority research questions identified by Creative Forces in art therapy and music therapy. Creative Forces initially issued Requests for Applications (RFAs) for feasibility/pilot studies, resulting in four studies: two in art therapy and two in music therapy. The current RFA announces a subaward for a Randomized Controlled Trial (RCT) or large-scale prospective study. The research is intended to address one of two priority research questions (below) and to yield generalizable findings about the impacts of including art therapy¹ or music therapy² in common clinical practice — as stand-alone interventions or within interdisciplinary care — with military populations. Military populations in this context include service members and veterans. The entire research budget for this study is \$900,000 over a period of 32 to 34 months. No additional funding for indirect costs is available. Any funding for indirect costs must come out of the research budget.

¹ **Art therapy** is defined by the American Art Therapy Association (https://arttherapy.org/) as a mental health and human services profession that enriches the lives of individuals, families, and communities through active art-making, the creative process, and applied psychological theory and human experience within a psychotherapeutic relationship facilitated by a qualified, credentialed art therapist.

² **Music therapy** is characterized by the American Music Therapy Association (https://www.musictherapy.org/) as the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program, clinical internship, and earned board- certification as a music therapist.

PRIORITY RESEARCH QUESTIONS: Proposed studies must address the priority research questions identified in the Creative Forces Conceptual Frameworks Phase 2 Final Report (https://www.creativeforcesnrc.arts.gov/system/files/2023-
03/CreativeForcesConceptualFrameworksPhase2ExecutiveReport2020.pdf)

MUSIC THERAPY: How, through what mechanisms, and to what extent does music therapy affect the discomfort, disability, and quality of life associated with chronic pain in service members and/or veterans experiencing chronic pain?

ART THERAPY: How, through what mechanisms, and to what extent does art therapy affect emotional processing, self-regulation, and other symptoms of traumatic stress for service members and/or veterans?

ISSUING ORGANIZATION: Creative Forces is managed in partnership with the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF) (https://www.hjf.org).

PARTICIPATING ORGANIZATIONS: Creative Forces (https://www.creativeforcesnrc.arts.gov); National Endowment for the Arts (https://www.arts.gov).

RFA NUMBER: CF-2023-RCT-01

ANNOUNCEMENT TYPE: This is a one-time, phased award opportunity for an RCT or large-scale prospective study. It is not part of an ongoing award cycle.

LETTER OF INTENT SUBMISSION: Applicants must submit a Letter of Intent (LOI) via email in advance of their application, per the instructions in Section V.

APPLICATION SUBMISSION: Applications must be submitted via PDF, per instructions in <u>Section VI</u>. Applications may not be submitted in paper format.

REQUEST AN APPLICATION AND REQUIRED FORMS: Required application forms and any required templates are available for download from the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy) or can be obtained by contacting Enka Sodnom at esodnom@hjf.org.

RFA CONTACTS: General RFA contacts:

Scientific/research contact: Dr. Jay Uomoto, Creative Forces Clinical Research Director, <u>juomoto@hjf.org</u>
Financial management contact: Enka Sodnom, HJF Subcontracts Administrator, <u>esodnom@hjf.org</u>

II. KEY DATES

KEY DATES: Key dates for this RFA are provided in the table below.

QUESTIONS: We welcome all questions from applicants. Refer to the table for details.

Event	Date	Additional Information
RFA release	March 15, 2023	Download RFA and application forms on the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy) or contact Enka Sodnom (esodnom@hjf.org).
Q&A submissions	Accepted until April 21, 2023 3:00 pm (EDT)	Questions must be submitted via email to Dr. Jay Uomoto (<u>juomoto@hjf.org</u>).
Q&A responses	Posted by May 1, 2023 3:00 pm (EDT)	Answers to Q&A submissions will be posted on the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy)
Letter of Intent (<i>Required</i>)	Due May 16, 2023 3:00 pm (EDT)	LOI must be submitted via email to Dr. Jay Uomoto (juomoto@hjf.org) using the LOI form provided on the Creative Forces National Resource Center (https:// www.creativeforcesnrc.arts.gov/news/ research-funding-available-art-therapy- and-music-therapy). See Section V.
Application period closes	Due May 30, 2023, 3:00 pm (EDT)	Submit per instructions in Section VII.
Subaward notification	July 15, 2023	
Study period	August 30, 2023 – June 30, 2026	

III. ELIGIBILITY/REQUIREMENTS

ELIGIBILITY: U.S. states and territories-based organizations, and researchers or clinicians with the skills, knowledge, and resources necessary to carry out the proposed research as the Principal Investigator (PI). All applicants must have a Unique Entity Identifier (UEI) created in the System for Award Management (https://sam.gov), be registered with the System for Award Management, and maintain an active SAM registration until the application process is complete, and should a subaward be made, throughout the life of the subaward.

A Creative Forces music or art therapist may serve as an interventionalist to the study population (provide experimental and/or control therapy services) and may serve in other research roles, as determined by the music or art therapist and other members of the research team. The music/art therapist's salary and benefits are already accounted for by existing arrangements between Creative Forces and HJF. Thus, a Creative Forces music/art therapist's research activity will be provided at no cost to the subaward budget. Please note that the Creative Forces music/art therapist's amount of effort may be limited due to other assigned clinical duties beyond the research effort. The team may

include other music/art therapists/interventionalists, depending on the necessity as articulated in the research protocol. These therapists should be accounted for in the research budget.

INSTITUTIONAL SUPPORT: Applicants are required to submit a letter of institutional support with their application, demonstrating the commitment of their institution and summarizing the agreements they have, or will have, in place to support the study. Full requirements are in <u>Section VI.A.7</u>.

IV. RESEARCH SUBAWARD DETAILS

CREATIVE FORCES RESEARCH: Creative Forces invests in research on the physical, emotional, and social benefits of creative arts therapies as innovative treatment methods. Creative Forces is committed to the pursuit and promotion of clinically-relevant biomedical and behavioral research on the effectiveness of creative arts therapies for service members and veterans, as well as for their family members and caregivers. Several strategies are critical to the success of our research program. They include: informed selection of rigorous research designs; support for multisite studies; funding of research opportunities at Creative Forces sites; and collaboration with other health/rehabilitation disciplines and partners. See https://www.creativeforcesnrc.arts.gov/our-impact/clinical-research-findings for additional information, including the Creative Forces Clinical Research Strategic Framework and Five-year Agenda, and existing research at Creative Forces sites. The Creative Forces Conceptual Frameworks Phase 2 Final Report, a pertinent resource for subaward applicants, can be found at

https://www.creativeforcesnrc.arts.gov/system/files/2023-

<u>O3/CreativeForcesConceptualFrameworksPhase2ExecutiveReport2020.pdf</u>. With this funding opportunity, Creative Forces is investing in research that ultimately aims to lead to generalizable findings about the impacts of art therapy or music therapy in common clinical practice, including the scalability of such interventions and benefits across multiple treatment sites.

PURPOSE AND STRATEGY: This subaward is intended to advance **systematic music therapy or art therapy research** for **military populations** by supporting an RCT or large-scale prospective study. As noted in <u>Section I</u>, Creative Forces is seeking proposals to address either of the following research questions:

MUSIC THERAPY: How, through what mechanisms, and to what extent does music therapy affect the discomfort, disability, and quality of life associated with chronic pain in service members and/or veterans experiencing chronic pain?

ART THERAPY: How, through what mechanisms, and to what extent does art therapy affect emotional processing, self-regulation, and other symptoms of traumatic stress for service members and/or veterans?

FUNDS AVAILABLE: A subaward up to \$900,000 for a study period of 32 to 34 month for an RCT or large-scale prospective study **will be awarded incrementally in three phases.**

V. LETTER OF INTENT TO SUBMIT (*REQUIRED*)

LETTER OF INTENT: All applicants must submit a Letter of Intent (LOI) in advance of their proposal. The LOI must be submitted via email to Dr. Jay Uomoto (<u>juomoto@hjf.org</u>) and **received by May 16**, **3:00 pm (EDT). The required LOI form is provided on** the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy).

The LOI must include: Principal Investigator(s) with institutional affiliation, partners with institutional affiliation, the Creative Forces priority research question the study will address, and a brief abstract of the study.

VI. APPLICATION REQUIREMENTS

This application is for a subaward for a randomized controlled trial (RCT) or large-scale prospective study. Applicants must submit a Letter of Intent in advance of their proposal (see <u>Section V</u>.)

PROPOSAL REQUIREMENTS (see required application form for instructions and word/page limits by item):

A. Description of Participating Entities

- 1. *Principal Investigator(s):* Name, title, address, phone number, email.
- 2. *PI Institution/Organization:* Name, address, website; authorizing official name, title phone number, email.
- 3. Creative Forces Partner (if applicable): Creative Forces site; lead contact name, title, phone number, email; music and/or art therapist name, title, phone number, email. Creative Forces Collaboration/Partnership Description: Describe the roles and responsibilities and what each partner brings to the collaboration. Include information of the history of collaboration between partners, if any.
- 4. Additional Partner (if applicable): Name, institution, title, address, phone number, email. Collaboration/Partnership Description(s): Describe the roles and responsibilities and what each partner brings to the collaboration. Include information of the history of collaboration between partners, if any.
- 5. **Letter(s) of Collaboration:** Signed by the PI and 1) for partnerships with Creative Forces, by the site's Creative Forces director and music and/or art therapist(s) providing services for the study; 2) for other partnerships, signed by equivalent personnel (attach as separate document; see Section VI.D).
- 6. Biosketches: For Principal Investigator(s) and all collaborators/partners, supervisors central to creation of the proposal, using the provided template. The template can be obtained on the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy) or by contacting Enka Sodnom (esodnom@hjf.org) (attach as separate document; see Section VI.D).
- 7. **Letter(s) of institutional support:** At a minimum, letters should be signed by 1) the PI, 2) the facility director, 3) the chief of research, or clinical supervisor, or equivalent (attach as separate document; see Section VI.D).

NOTE: At a minimum, letters/agreements should stipulate expectations for level of effort, responsibilities, co-authorship, access to core facilities/resources, and fees-for-service *as appropriate to the relationship*. Institutional Review Board approvals and data-sharing agreements are not expected at the time of application but should be addressed in the study timeline and implementation plans.

- B. Research Strategy: Sections B3 B7 should not exceed 6 pages. All other sections should adhere to word limits specified in the application form.
 - 1. Title: Study title.
 - 2. **Abstract**: Briefly describe the RCT or large-scale prospective study.
 - 3. Background and Significance: Briefly sketch the background for your research question. Critically evaluate existing knowledge (published literature, clinical trials, etc.) and identify specific gaps the project intends to fill. How will this research advance scientific knowledge and/or clinical practice? Describe the effect of this research on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field. Describe any new methodology and its advantage over existing methodologies, and/or novel concepts, approaches, tools, or technologies. Explain how the proposed study helps to answer the selected Creative Forces priority research question in music or art therapy.
 - 4. **Question/Hypotheses**: Identify the research question(s) and hypothesis for the RCT or large-scale prospective study.
 - 5. Research Design and Methods: This section should provide a clear understanding of the research design, procedures, and analyses. A power analysis should be included. This section must include:
 - a. Research Design: Description of the research design, including how the specific aims are best addressed with the proposed research design. Include an explanation of how the results of the RCT or large-scale prospective study can potentially inform the impacts of music or art therapy in common clinical practice.
 - b. Study Population: Describe the study population from which recruitment is aimed. State the number of participants and include a power analysis to justify this number. Based upon prior experience or other similar studies, estimate the attrition rate and include the number needed to enroll to achieve the desired number of participants.
 - c. **Intervention**: Description of intervention including activity; number, length, and frequency of sessions; and the length of a follow-up period if applicable. Include procedures for monitoring and reporting treatment fidelity.
 - d. **Location**: Location of study/intervention activities.
 - e. **Participant Recruitment**: Describe participant recruitment strategies, including control groups if applicable. Include additional or alternative recruitment strategies should planned recruitment fall short of expected benchmarks.
 - f. **Participant Selection**: Describe participant selection, including data describing the inclusion/exclusion criteria at the recruiting site(s) and number(s) of potential participants available. The proposal should provide evidence of the feasibility of recruiting the sample, based on recruitment timeline, the number of participants needed to reasonably evaluate study objectives, and potential budget restrictions.
 - g. **Measures**: Describe and justify measures used in the study.
 - h. **Data Collection Methodology**: Describe data collection tools and methods and their appropriateness to the research design.
 - i. **Data Analysis Plan**: Describe the statistical approach and interpretation that will be used to answer the questions under investigation.

- j. **Data Management Plan**: Describe plans for data access, sharing, protection/privacy, and archiving.
- k. Interpretation: Potential results and interpretations.
- Timetable: Provide a timetable for the project (preparation for the study, IRB, recruitment, intervention, data analysis). Use a Gantt Chart or other similar format.
- m. **Limitations and Alternative Approaches**: Describe potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the study's aims.
- n. **Dissemination Plan**: Describe the plan to disseminate the results from this research, such as publishing briefs, presenting findings at a national conference, publishing in an academic journal, etc., and the target audience.
- 6. **Research Facilities/Resources/Equipment:** Describe facilities and other physical resources for the research.
- 7. **Risk Assessment:** Identify any procedures, situations, or materials that may be hazardous to participants and the precautions to be exercised, and activities and strategies to minimize risk.
- **C. Budget:** The RCT or large-scale prospective study will be incrementally funded over the subaward period of 32 to 34 months. The total budget cannot exceed a total of \$900,000, including indirect costs. **Funding is to be provided in the following increments:**

Phase 1: August 2023-May 2024 - \$200,000 Phase 2: June 2024-May 2025 - \$350,000 Phase 3: June 2025-April 2026 - \$350,000

Note that no additional funds are available to pay for institutional indirect costs. No cost sharing or matching is required. Detailed budget guidelines and required templates for the budget and justification can be obtained on the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy) or by contacting Enka Sodnom (esodnom@hjf.org). Note that Creative Forces clinicians' salaries and benefits are already covered by pre-existing employment arrangements by Creative Forces/ Henry M. Jackson Foundation for the Advancement of Military Medicine. This subaward cannot be used to pay federal salaries.

- 1. *Itemized Budget*: Provide an itemized budget and budget justification for the study using the provided templates.
- D. Required Supporting Documents (described above) to be submitted as email attachments.
 - 1. **Biosketches**: (5-page max in format provided in the template) for each Principal Investigator and all collaborators/partners.
 - 2. *Itemized Budget and Justifications*: Using the required templates for the budget and justification, provide detailed budget guidelines.
 - 3. **Letter(s) of Collaboration**: Signed by the PI and 1) for partnerships with Creative Forces, by the site's Creative Forces director and music and/or art therapist(s) providing services for the study; 2) for other partnerships, signed by equivalent personnel.

- 4. *Institutional Letters of Support*: At a minimum, letters should be signed by 1.) the PI, 2.) the facility director, 3.) the chief of research, or clinical supervisor, or equivalent.
- 5. **Additional Letters of Support (optional):** Attach any additional letters necessary to demonstrate the support of key contributors, senior personnel, and/or collaborators.

VII. SUBMISSION PROCESS

APPLICATION: Applications (required application form and <u>Section VI.D</u> attachments) **must be received by May 30 by 3:00 pm (EDT).** Submit applications via PDF to Enka Sodnom (<u>esodnom@hjf.org</u>). **NOTE**: Submission packages less than 10MB can be submitted via email. If larger than 10MB, please contact Enka Sodnom (<u>esodnom@hjf.org</u>) for a secure link to upload your proposal.

VIII. SELECTION AND NOTIFICATION

Creative Forces is investing in advancing systematic, rigorous music and art therapy research for military populations. We are seeking robust projects that will create new knowledge and enable breakthroughs in understanding how music therapy and art therapy affect outcomes for military populations. To identify which projects to support, Creative Forces will rely on a merit review process that incorporates consideration of both the scientific and technical aspects of a proposed project and its potential to contribute to the Creative Forces research mission.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Creative Forces Research Leadership Team and in accordance with the review criteria stated below. Creative Forces will make every effort to conduct a fair, competitive, transparent review process for the selection of projects.

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance to program priorities.

Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. Proposals will be evaluated for the following scientific and technical merit criteria, according to the weights indicated for each criterion.

Scientific Merit: Proposals will be reviewed for their alignment with Creative Forces research and clinical priorities and the indicated priority research question in art or music therapy provided in <u>Section IV</u>. The following criteria will be considered.

- Significance/Relevance to Military Populations (15%): Will this research significantly advance knowledge as to what extent and how music therapy or art therapy impacts military populations?
- Research Question/Hypothesis, Rationale, and Progression (20%): Is the research
 question/hypothesis of the RCT or large-scale prospective study responsive to the Creative
 Forces prioritized research question? Is it backed by a strong evidence-based rationale?

• Research Design and Methodology (20%): Does the proposal address all required elements of the Research Design and Methods (Section VI.B.5)? Is the research design scientifically justified and appropriate to address the research question(s) for the RCT or large-scale prospective study hypotheses? Are the methods and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Is the approach feasible in the timeframe provided? Is the approach rigorous?

Technical Merit: Proposals will be reviewed for their technical merit; specifically, the technical properties needed to carry out the proposed study with rigor and excellence.

As indicated in the Application Section (VI), a thorough and detailed description is required for the RCT or large-scale prospective study (Section VI.B.5).

- Investigative Team and Project Management (15%): Is the investigative team appropriately trained and well-suited to carry out the study? Does the investigative team bring complementary and comprehensive expertise to the project? Is the experience level of the PI and other team members appropriate to the proposed study? For newly-formed teams, is there sufficient evidence that the team can collaborate successfully? Are project management roles defined?
- **Partnerships (10%)**: Are the necessary partnerships in place and of sufficient strength to support the research? Are partnerships defined, with designated roles and responsibilities consistent with and justified by the aims of the project and the expertise of each partner? If applicable, is the partnership with the clinical/research site established and defined?
- Research Environment (10%): Does the research have sufficient institutional support? Does the
 scientific/clinical environment (or environments) in which the work will be done contribute to
 the probability of success? Is the availability of resources such as equipment, facilities, and
 trained staff to use the equipment/facilities demonstrated? Does the proposed study benefit
 from unique features of those environments, or subject populations, or employ useful
 collaborative arrangements?
- Limitations and Alternative Approaches (5%): Does the proposal identify potential difficulties and limitations of the proposed procedures? Are alternative approaches appropriate to achieve the aims?
- **Risk Management Plan (5%)**: How are procedures, situations, or materials that may be hazardous to participants addressed? Are there precautions to be exercised, and activities and strategies to minimize risk appropriate and feasible?

IX. CONDITIONS OF THE SUBAWARD

FUNDING DISTRIBUTION: The RCT/Large-Scale Prospective Study will be incrementally funded over the subaward period.

TECHNICAL REPORTING: Subrecipients will be required to submit brief progress reports at the end of the first and second funding periods and a final report at the end of the subaward, including plans for sharing research outcomes. The Henry M. Jackson Foundation will provide reporting templates.

AGREEMENT TYPE: Subaward Agreements will be issued in accordance with Uniform Guidance (2 CFR 200 - UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS).